REMARKS

Summary of the Office Action

Claims 1-6 are pending. Claims 2 and 3 are allowed. Claims 5 and 6 are rejected under 35 U.S.C. § 101, claims 1 and 4-6 are rejected under 35 U.S.C. § 112, second paragraph, and claims 4-6 are objected to under 37 C.F.R. § 1.75(c). By this reply, Applicants amend claims 4-6, and address each of the Examiner's rejections and objections below. Applicants respectfully request reconsideration of the claims based on the following remarks.

Support for the Amendment

Support for the amendment to claims 4-6 is found on page 2, line 23, through page 4, line 6. No new matter is added by the amendment.

Summary of the Invention

The invention features ceramide analog compounds of the general formula (I), processes for their preparation, and uses thereof in the preparation of pharmaceutical formulations for the treatment of tumors.

Information Disclosure Statement

The Examiner states that the references in the specification are not listed in a proper information disclosure statement. Accordingly, Applicants submit herewith an information disclosure statement and form PTO 1449 listing these references.

Specification

The Examiner states that "[a]n application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification..." Applicants have amended the specification to claim priority under 35 U.S.C. § 371 to PCT Application PCT/EP00/07023, filed July 21, 2000, which claims priority to Italian Patent Application No. FI99A000169, filed July 22, 1999.

Objections

The Examiner objects to claims 4-6 under 37 C.F.R. § 1.75(c) because "a multiple dependent claim should refer to other claims in the alternative only." Applicants have amended claims 4 and 5 to recite proper dependency in the alternative. Accordingly, this objection should be withdrawn.

Rejections under 35 U.S.C. § 101

Claims 5 and 6 stand rejected under 35 U.S.C. § 101 "because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process." Applicants have amended claim 5 to recite a method of making a pharmaceutical composition for the treatment of a tumor by admixing the compound of claim 1, 2, or 3 with a pharmaceutically acceptable excipient or diluent. Claim 6 has been amended to recite a method for treating a tumor in a mammal by administering the composition of claim 4. Therefore, claims 5 and 6 now set forth steps involved in making a pharmaceutical composition and using the pharmaceutical composition, respectively. Accordingly, Applicants respectfully request that

the rejection of claims 5 and 6 under 35 U.S.C.§ 101 be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1 and 4-6 are rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. The Examiner asserts that "[t]he term 'saccharidic portions' in claim 1, line 9, has not been defined in such a way as to apprise the skilled artisan in the filed of the metes and bounds of the claimed invention. In the absence of such [a] definition, the term 'saccharidic portions' is indefinite in all occurrences." Applicants respectfully traverse this rejection.

The term "saccharidic portions" is well known in the art and refers to a sub-class of carbohydrates (i.e., the commonly called "simple carbohydrates" or, more properly, "sugars" or "saccharides"). This family comprises a number of well known, structurally homologous compounds characterized in that they are substantially polyhydroxy aldehydes or ketones usually existing in a 5-6 member cyclic hemiacetal form. They are further classified into monosaccharides, disaccharides, or polysaccharides, depending on the number of elemental units that form their structure. See, for example, pages 1-3 and 5 of "The Carbohydrates" (Edited by Ward Pigman, 1957, Academic Press, NY) and pages 737, 737, and 739-742 of "Organic Chemistry" (Henry Rakoff and Norman C. Rose, 1966, The Macmillan Company, NY; submitted herewith as Exhibit A and Exhibit B, respectively). Based on these representative references, which were published long before the above-referenced application was filed, Applicants submit that the term "saccharidic portions" is well known to the skilled artisan, who would clearly understand that the term refers to the above-mentioned class of sugars.

This definition of the term "saccharidic portions" is also consistent with the text of the

application. See, e.g., Example 23, page 24. The specification states that compound 23 contains as substituent R_2 a benzyloxy derivative of glucose, the most widely distributed monosaccharide. Furthermore, the specification also discloses compound 25, which also contains a glucose as substituent R_2 (see Example 24, page 26, lines 15-19). Because it is ubiquitous in nature, glucose was chosen for use in the Examples as the preferred representative of the whole class defined by the term "saccharidic portions."

For these reasons, a skilled artisan would have understood, based on the knowledge in the art and the teaching in the specification, the meaning of the term "saccharidic portions." Accordingly, Applicants respectfully request that the rejection of claims 1 and 4-6 be withdrawn.

The Examiner also rejects claims 5 and 6 under 35 U.S.C. § 112, second paragraph, for lack of clarity. The Examiner states that "[c]laims 5 and 6 provide for the use of the compounds of the general formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass." Applicants have amended claims 5 and 6 to appropriately clarify the intended method. Accordingly this rejection should be withdrawn.

CONCLUSION

In light of the foregoing amendments and remarks, Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including March 10, 2003, and a check for $930.00 in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Version with markings to show changes made

4. (Amended) A pharmaceutical composition suitable for administration to a mammal comprising the compound of any one of claim 1, 2, or 3, or a pharmaceutically acceptable derivative or salt thereof, admixed with a pharmaceutically acceptable excipient or diluent. [Pharmaceutical preparations including as their active ingredient at least one of the compounds of the general formula (I) described in claims 1-3, and/or their pharmaceutically acceptable derivatives or salts, together with excipients and/or diluents.]

5. (Amended) A method of making a pharmaceutical composition for the treatment of a tumor, said method comprising admixing the compound of any one of claim 1, 2, or 3 with a pharmaceutically acceptable excipient or diluent. [Use of the compounds of the general formula (I) described in claims 1-3 for the preparation of pharmaceutical formulations.]

6. (Amended) A method for treating a tumor in a mammal by administering the composition of claim 4. [The use according to claim 5, for the preparation of pharmaceutical formulations for use in the treatment of tumours.]